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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/876,144 | 06/08/2001 | David Hung | 05284.00092 | 6700 |

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EXAMINER

KIM, JENNIFER M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1617 | 8 |

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/876,144 | HUNG ET AL. |
| | Examiner | Art Unit |
| | Jennifer M Kim | 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 May 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
 - 4a) Of the above claim(s) 2-5 and 11 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 6-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Applicants' election without traverse of Group I, Claims 1 and 6-10, drawn to a composition to contact a breast nipple and to prepare a breast for ductal fluid collection comprising two or more of the active agents in Paper No. 6 is acknowledged.

Accordingly, non-elected invention of Group II, Claims 2-5 and 11 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 6 and 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

The phrase "**mixture of one**" in claim 6 is vague and indefinite since you need **two or more** ingredients or active agents to form a mixture.

The term "system" in claim 9 is indefinite since it is not clear what the "system" encompasses since the term is not defined in the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 6 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Tian (CN 1252293A) in view of Merck Index (1983).

Tian teaches medicated pad comprising alcohol that acts on breast directly to prevent and treat breast disease.

Merck Index on page 34, No. 211, teaches that alcohol as antiseptic agent.

Applicants' recitation in claim 8 of an intended use of a system to contact with a nipple surface and covering nipple surface for sufficient time for the bioactive agent to act on the nipple surface not found in the prior art does not represent a patentable limitation since such fails to impart any physical limitation to the composition that is not found in the prior art composition.

5. Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Zupan (U.S. Patent No. 4,560,553). Zupan on column 3, line 57- column 4, line 5, and column 13, lines 35-57, teaches a composition comprising biologically effective amounts of local anesthetics and beta-blockers formulated in solution.

Applicants' recitation in claims 1, 6 and 7 of an intended use of contacting a breast nipple and preparing a breast for ductal fluid collection not found in the prior art does not represent a patentable limitation since such fails to impart any physical limitation to the composition that is not found in the prior art composition.

6. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Tabar et al.

Tabar et al. on the abstract and page 31 right-hand column, teach intraductal injection comprising a standard needle (ductal access tool) comprising methylene blue **dye** and contrast material can make surgery unnecessary in patients with intraductal tumors.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tabar et al.

Tabar et al. on the abstract and page 31 right-hand column, teach intraductal injection comprising a standard needle (ductal access tool) comprising methylene blue **dye** and contrast material can make surgery unnecessary in patients with intraductal tumors.

Tabar et al. on page 36 middle column, teach the above intraductal administration procedure is painful.

The difference between above reference and Applicants' claimed invention is formulating the needle with preloaded anesthetic. However, to formulate the needle with preloaded anesthetic would have been obvious to skilled artisan since the procedure is painful as stated by Tabar et al. The skilled artisan would have been motivated to formulate the needle with preloaded anesthetic to ameliorate the pain caused by the procedure.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as

represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer M Kim whose telephone number is 703-308-2232. The examiner can normally be reached on 8:30AM - 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Russell Travers
Primary Examiner
Art Unit 1617

jmk
July 15, 2002